

USSN 10/620,000, filed July 14, 2003  
Attorney Docket No. 1103326-0250(CON)  
Page 2 of 9

### **AMENDMENT TO THE CLAIMS**

**This listing of claims will replace all prior versions, and listings, of claims in the application:**

1. (Currently amended) A tablet formulation comprising:

- (a) as a first component**, an acid susceptible proton pump inhibitor,
- (b) as a separate second component, at least one [or more]** Non Steroidal Antiinflammatory **Drug (NSAID)** [Drugs (NSAID(s))], and
- (c) as an optional third component, one or more [optionally,]** pharmaceutically acceptable excipients,

wherein [at least] the **first component** [proton pump inhibitor] is protected by an enteric coating layer, **and wherein the second component is separated from the first component by the enteric coating layer protecting the first component.**

Claim 2. (Canceled)

Claim 3. (Canceled))

4. (Currently amended) The tablet formulation according to claim 1, further comprising a **separating** layer separating the enteric coating layer from the proton pump inhibitor.

5. (Previously presented) The tablet formulation according to claim 1, wherein the tablet formulation comprises the proton pump inhibitor and one NSAID.

6. (Currently amended) The tablet formulation according to claim 1, wherein the proton pump inhibitor is **selected from the group consisting of** omeprazole, an alkaline salt of omeprazole, a single enantiomer of omeprazole **and** [or] an alkaline salt of the single enantiomer.

7. (Previously presented) The tablet formulation according to claim 6, wherein the proton pump inhibitor is S-omeprazole magnesium salt.

USPN 10/620,000, filed July 14, 2003  
Attorney Docket No. 1103326-0250(CON)  
Page 3 of 9

8. (Currently amended) The tablet formulation according to claim 1, wherein the proton pump inhibitor is selected from the group consisting of lansoprazole, a pharmaceutically acceptable salt of lansoprazole, a single enantiomer of lansoprazole and [or] a pharmaceutically acceptable salt of the single enantiomer.

9. (Currently amended) The tablet formulation according to claim 1, wherein the proton pump inhibitor is selected from the group consisting of pantoprazole, a pharmaceutically acceptable salt of pantoprazole, a single enantiomer of pantoprazole and [or] a pharmaceutically acceptable salt of the single enantiomer.

10. (Currently amended) The tablet formulation according to any one of claims 6-9, wherein the NSAID [NSAID(s)] is selected from the group consisting of ibuprofen, diclofenac, piroxicam, naproxen and pharmaceutically acceptable salts thereof.

11. (Previously presented) The tablet formulation according to any one of claims 6-9, wherein the NSAID is diclofenac or piroxicam, or a pharmaceutically acceptable salt thereof.

12. (Currently amended) The tablet formulation according to claim 1, wherein the amount of the proton pump inhibitor is in the range of 10-80 mg and the amount of the NSAID [NSAID(s)] is in the range of 10-800 mg.

13. (Currently amended) The tablet formulation according to claim 1, wherein the amount of the proton pump inhibitor is in the range of 10-40 mg and the amount of the NSAID [NSAID(s)] is in the range of 10-500 mg.

14. (Currently amended) The tablet formulation according to claim 1, wherein the tablet formulation further comprises a first and second layer, and wherein the first layer comprises the first component [proton pump inhibitor] and the second layer comprises the second component [one or more NSAID(s)].

Claims 15-21 (Canceled)

22. (Currently amended) The tablet formulation according to claim 1, wherein the tablet formulation further comprises a first and second layer, and wherein the first layer comprises the proton pump inhibitor in the form of enteric coating layered pellets and tablet excipients, and the second layer comprises the NSAID [NSAID(s)].

USSN 10/620,000, filed July 14, 2003  
Attorney Docket No. 1103326-0250(CON)  
Page 4 of 9

Claim 23. (Canceled)

Claim 24. (Canceled)

25. (Currently amended) The tablet formulation according to claim 1, wherein the proton pump inhibitor is in the form of enteric coating layered pellets compressed to a tablet which [and the tablet formulation] is covered by a layer comprising the NSAID [NSAID(s)].

26. (Currently amended) The tablet formulation according to claim 25, wherein the layer comprising the NSAID [NSAID(s)] is covered by a pigmented tablet filmcoating layer.

27. (Currently amended) The tablet formulation according to claim 1, wherein the proton pump inhibitor is in the form of enteric coating layered pellets, and the NSAID [NSAID(s)] is in the form of enteric coating layered pellets.

28. (Currently amended) The tablet formulation according to claim 1, wherein the proton pump inhibitor is in the form of enteric coating layered pellets, and the NSAID [NSAID(s)] is in the form of pellets coating layered with an extended release film.

Claims 29-32 (canceled)

33. (Currently amended) A method for the treatment of gastrointestinal side-effects associated with NSAID treatment in mammals and man by administering to a host in need thereof a therapeutically effective dose of the tablet formulation according to any one of claims 1, 4-14, 22, or 25-28 [4-9, 12-14 or 22-28].

34. (Previously presented) The method according to claim 33, wherein the disorder is an upper gastrointestinal disorder associated with NSAID treatment.

Claim 35. (Canceled)

Claim 36. (Canceled)

37. (Previously presented) The tablet formulation according to any one of claims 6-9, wherein the NSAID is a NO-releasing NSAID, salt, hydrate, or ester thereof.

38. (Previously presented) The tablet formulation according to claim 37, wherein the NO-releasing NSAID is selected from the group consisting of NO-releasing diclofenac and NO-releasing naproxen.

USSN 10/620,000, filed July 14, 2003  
Attorney Docket No. 1103326-0250(CON)  
Page 5 of 9

39. (Previously presented) The tablet formulation according to any one of claims 6-9, wherein the NSAID is acetyl salicylic acid.

40. (Previously presented) The tablet formulation according to any one of claims 6-9, wherein the NSAID is a (COX)2 selective NSAID, salt, hydrate or ester thereof.

41. (Currently amended) The tablet formulation according to claim 22, wherein the second layer gives an extended release of the **NSAID** [NSAID(s)].

42. (Currently amended) The tablet formulation according to claim 41, wherein the second layer further comprises a gelling matrix giving an extended release of the **NSAID** [NSAID(s)].

43. (Currently amended) The tablet formulation according to any one of claims 22, [23,] 25-28, 41 or 42 wherein the acid resistance of the enteric coating layered pellets comprising the proton pump inhibitor is in compliance with the requirements on enteric coating layered articles defined in the United States Pharmacopeia.

44. (Currently amended) The tablet formulation according to any one of claims 22, [23,] 25-28, 41 or 42 wherein the acid resistance of the enteric coating layered pellets comprising the proton pump inhibitor does not decrease more than 10% **during compression of the enteric coating layered pellets into the multiple unit tablet formulation** ~~in compliance with the requirements on enteric coating layered articles defined in the United States Pharmacopeia.~~

45. (Currently amended) The tablet formulation according to any one of claims 22, [23,] 25-28, 41 or 42 wherein the enteric coating layer of the individual pellets comprises a plasticizer.